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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/721,144 | 11/25/2003 | Robert J. Hariri | 9516-495-999 /501872-494 | 6313 |

84802 7590 09/14/2010

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| EXAMINER | |
|---|---|
| HIBBERT, CATHERINE S | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 09/14/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/721,144 | HARIRI, ROBERT J. | |
| | Examiner | Art Unit | |
| | CATHERINE HIBBERT | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,5,6,12,13,15-18,20-23,31,32 and 34-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,12,13,15-18,20-23,31,32 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/2010; 8/26/2010; 8/26/2010; and 8/27/2010* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's Amendment to the Claims filed on 18 June 2010 has been received and entered. Claims 2-4, 7-11, 14, 19, 24-30, 33, and 38-57 are cancelled. Claims 1, 5, 6, 12, 13, 15-18, 20-23, 31, 32, and 34-37 are pending and under examination in this action.

All rejections to currently cancelled claims 54-57 are moot and all other objections and rejections not repeated herein are withdrawn.

### *Priority*

Priority to the instantly claimed invention is granted to US Provisional 60/429,702, filed 11/26/2002.

### *Information Disclosure Statement*

Applicant's submission of the IDS statements on 6/24/2010; 8/26/2010; 8/26/2010; and 8/27/2010 have been received and have been considered by the examiner.

### *Claim Rejections - 35 USC § 102-maintained*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Currently amended Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Strom et al in "Placental derived stem cells and uses thereof" (USPGPub2003/0235563, priority to US Provisional 60/374,172, filed 19 April 2002, entire document) for reasons of record and presented herein.

Currently amended claim 1 is drawn to a cytotherapeutic unit comprising at least 1% CD34+ cells within a plurality of potent cells, the unit comprising cells from a plurality of sources, "wherein said plurality of potent cells comprises isolated CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells".

Strom et al teach cytotherapeutic units for treatment of patients (including hematopoietic cells) the cell compositions comprising at least 1% CD34+ cells within a plurality of potent cells (i.e. CD34+ and OCT-4+ cells and SSEA4+ cells and SSEA3+ cells and SSEA3- cells and CD34- cells), the unit comprising cells from a plurality of sources (e.g. cells obtained from the amnion, chorion and decidual layers of the placenta [e.g. abstract, claim 1 and paragraph 0047]). Edinger et al (US 2007/0275362, published 29 November 2007; made of record in the IDS filed 8/27/2010) provides evidence that placental stem cell populations inherently contain CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells (e.g. paragraph 0064, line 1; para.0085, lines 1-3; para. 0091, line 2; para. 0157) and thus, absent evidence to the contrary, the placental stem cell compositions of Strom et al would inherently contain each of the claimed cell types.

**Applicant's response** is to traverse the rejection and argue that the current claim amendment to claim 1 to incorporate the limitations of currently cancelled claim 54 is sufficient to overcome the Strom et al reference.

Applicant's arguments have been fully considered but are unpersuasive.

Claim 1 is currently amended to recite: "wherein said plurality of potent cells comprises isolated CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells" in lines 3-5. As such, the claim now requires that the plurality of potent cells includes *all* of the cell types listed. However, contrary to applicant's argument, this amendment fails to incorporate the limitation of currently cancelled claim 54 which required all of the cell markers CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ to be present together, which is not required of the instantly amended claim 1.

Claims 1, 5, 6,12,13,15-18, 20-23, 31, 32, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Casper et al in "Cellular composition and methods of making and using them" (USPGPub2005/0074435, priority to US Provisional 60/342,586, filed 21 December 2001, entire document) for reasons of record and presented herein.

Currently amended claims 1, 18, 31 and 34 are drawn to cytotherapeutic units comprising cells from a plurality of sources, "wherein said plurality of potent cells comprises isolated CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells".

Casper et al teach cytotherapeutic units for treatment of patients (including hematopoietic cells) the cell compositions comprising at least 1% CD34+ cells within a plurality of potent cells (i.e. CD34+ and OCT-4+ cells and SSEA4+ cells and SSEA3+ cells and SSEA3- cells and CD34- cells), the unit comprising cells from a plurality of sources (e.g. cells obtained from umbilical cord blood [e.g. claims 1-3, 14, paragraph 0023]). Casper et al disclose the cord blood samples were isolated using procedures wherein at least one type of cell is excluded from the unit (e.g. paragraph 0213). Regarding claims 20-23, it would be inherent to label any cytotherapeutic unit intended for patient use according to the limitations of claims 20-23. Regarding claim 36, Casper et al teach cryopreservation of the cells (e.g. 0216).

**Applicant's response** is to traverse the rejection and argue that the current claim amendment to claims 1, 18, 31 and 34 to incorporate the limitations of currently cancelled claims 54-57 are sufficient to overcome the Casper et al reference.

Applicant's arguments have been fully considered but are unpersuasive.

Claims 1, 18, 31 and 34 are currently amended to recite: "wherein said plurality of potent cells comprises isolated CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells". As such, the claims now require that the plurality of potent cells includes *all* of the cell types listed. However, contrary to applicant's argument, this amendment fails to incorporate the limitation of currently cancelled claims 54-57 which required *all* of the cell markers CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ to be present together, which is not required of the instantly amended claims 1, 18, 31 and 34.

Erices et al (British J. of Haematology, 2000; of record) and Edinger et al (US 2007/0275362, published 29 November 2007; made of record in the IDS filed 8/27/2010) provide evidence that umbilical/fetal cord blood and placental stem cell populations inherently contain CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells (e.g. Erices et al page 239 and Edinger et al: paragraph 0064, line 1; para.0085, lines 1-3; para. 0091, line 2; para. 0157) and thus, absent evidence to the contrary, the placental stem cell compositions of Casper et al would inherently contain each of the claimed cell types.

Claims 1, 5, 6,12,13,15-18, 20-23, 31, 32, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Edinger et al (US 2007/0275362, published 29 November 2007; **made of record in the IDS filed 8/27/2010**). This is a new grounds of rejection.

Edinger et al teach cytotherapeutic units comprising cell compositions comprising at least 1% CD34+ cells within a plurality of potent cells (i.e. CD34+ and OCT-4+ cells and SSEA4+ cells and SSEA3+ cells and SSEA3- cells and CD34- cells), a mixture of placental stem cells and umbilical/fetal cord blood, with preferred embodiments including cells of CD34-, OCT-4+, SSEA3-, CD10+, CD29+, CD38-, C44+, CD44+, CD45-, CD54+, CD90+, SH2+, SH3+, SH4, SSEA4-, and ABC-p+ cells (e.g. paragraph 0064, line 1; para.0085, lines 1-3; para. 0091, line 2; ; para. 0096; para. 0157). Edinger et al disclose the cord blood samples were isolated using procedures wherein at least one type of cell is excluded from the unit (e.g. reference claim 32). Regarding claims 20-23, it would be inherent to label any cytotherapeutic unit intended for

patient use according to the limitations of claims 20-23. Regarding claim 36, Edinger et al teach cryopreservation of the cells (e.g. para. 0037).

***Double Patenting-maintained***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 6,12,13,15-18, 20-23, 31, 32, and 34-37 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims71-93 of copending Application No. 11/592,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because the amendments to the claims in the '544 application together with the amendments to the instant claims now present claims that are essentially identical except that the currently amended '544 claims now require postpartum placental perfusate which the currently amended instant claims no longer require. Thus, the '544

claims are now species claims that anticipate the genus of cytotherapeutic units of the instant base claims. In addition, the limitations in the dependent claims are essentially identical for both the instant and co-pending applications (e.g. require same cell types as identified by the same cell markers).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Applicant's response** is to traverse the rejection and argue that as Applicant estimates that upon entry of the present Amendment, the provisional rejection will be the only rejection remaining in the present application, that the provisional rejection will be withdrawn.

Applicant's arguments have been fully considered but are unpersuasive because for reasons provided above, the current claim amendment is not sufficient to overcome the standing prior art rejections and thus the provisional rejection is maintained.

## *Conclusion*

No claims are allowed.

Applicant's amendment to the claims on 6/18/2010 and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 8/27/2010 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

Catherine Hibbert
Examiner AU1636